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(56) Documents cited
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(58) Field of search
A5B

(54) **Pharmaceutical composition for the treatment of hair loss**

(57) A pharmaceutical composition for promoting scalp hair growth comprising an anti-androgen and a thyroid hormone, wherein preferably the anti-androgen comprises a mixture of an oestrogen e.g. oestradiol and a non-oestrogenic anti-androgen. The thyroid hormone may be triiodothyronine or thyroxine and the anti-androgen may be medroxyprogesterone acetate or cyproterone acetate.

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SPECIFICATION

Pharmaceutical composition for the treatment of hair loss

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The present invention relates to a pharmaceutical composition for preventing or arresting scalp hair loss and/or promoting scalp hair growth and in particular to a composition for topical application.

10 The present invention provides a pharmaceutical composition for preventing or arresting scalp hair loss and/or promoting scalp hair growth comprising an antiandrogen and a thyroid hormone. The compositions according to the invention may in general be used either by male or female patients.

An antiandrogen is herein defined as an agent which suppresses the secretion of androgens from either the adrenal glands or testes or ovaries either by suppressing pituitary gonadotrophin or ACTH/ secretion or reducing androgen secretion directly from the adrenal glands, ovaries or testes themselves, or is effective locally within the tissues by either displacing androgen from its tissue receptor or competing with its action, or which has an opposite action to androgens (e.g. oestrogen) or impairs the conversion of an androgen substrate to its biologically more active form as testosterone or dihydrotestosterone (e.g. 5 alpha reductase inhibitors such as progesterone), or inhibits in any other way the synthesis and/or the secretion and/or the action of androgens.

Preferably, a composition according to this invention includes at least one oestrogen, e.g. oestradiol or a pharmaceutically suitable derivative thereof such as oestradiol benzoate, or ethinyloestradiol, preferably in combination with at least one non-oestrogenic anti-androgen such as a progesterone-like compound e.g. medroxyprogesterone acetate or a similarly pharmaceutically acceptable derivative of medroxyprogesterone. Another suitable non-oestrogenic anti-androgen for use in the compositions according to this invention would be cyproterone acetate or another pharmaceutically suitable derivative of cyproterone. Although cyproterone acetate and medroxyprogesterone acetate are the preferred anti-androgens for use in the compositions according to the invention, other antiandrogens having a progesterone-like activity may suitably be employed. These include allyloestrenol, gestronol (e.g. as the hexanoate), dydro-gesterone, norgestrel, norethisterone, hydroxyprogesterone (e.g. as the hexanoate), or progesterone itself.

The thyroid hormone present in the preparations according to the invention is preferably triiodothyronine or a pharmaceutically suitable derivative or precursor thereof. Alternatively, the thyroid hormone may be thyroxine. Thyroxine exerts most, if not all, of its biological activity by conversion in the body to tri-iodothyronine.

60 The pharmaceutical compositions according to the invention are preferably formulated as creams, gels, ointments, pastes or lotions for topical application. For this purpose, any suitable carrier system normally employed in the preparation of such pharmaceutical compositions may be employed. For instance,

the ingredients may be dispersed in an ointment base such as "unguentum merck" or dissolved in a lotion base such as aqueous ethanol.

The compositions may suitably provide a concentration of anti-androgen of from 0.001 - 5% e.g. 0.01 to 2.5% by weight and a concentration of thyroid hormone suitable to provide from 2 - 200 µg per 3ml. 3ml is a typical single dose.

More preferably, the compositions may provide from 0.05 - 0.5% by weight anti-androgen, most preferably about 0.1% of each of an oestrogenic anti-androgen such as oestradiol benzoate and a non-oestrogenic anti-androgen such as medroxyprogesterone acetate.

80 Most preferably, the composition provides about 20 µg per 3ml dosage of the composition of triiodothyronine.

Such a formulation is suitably applied about twice a day to the areas in which it is desired to prevent or arrest scalp hair loss and/or promote scalp hair growth.

CLAIMS

90 1. A pharmaceutical composition for promoting scalp hair growth comprising an anti-androgen and a thyroid hormone.

2. A pharmaceutical composition as claimed in claim 1 wherein the thyroid hormone is thyroxine or triiodothyronine.

3. A pharmaceutical composition as claimed in claim 1 or claim 2 comprising as an anti-androgen a pharmaceutically acceptable derivative of medroxyprogesterone or cyproterone.

100 4. A pharmaceutical composition as claimed in claim 5 comprising as an anti-androgen medroxyprogesterone acetate or cyproterone acetate.

5. A pharmaceutical composition as claimed in any preceding claim or claim 2 wherein the anti-androgen comprises a mixture of an oestrogen and a non-oestrogenic anti-androgen.

6. A pharmaceutical composition as claimed in claim 5 wherein the oestrogen is oestradiol or a pharmaceutically acceptable derivative thereof.

110 7. A pharmaceutical composition as claimed in any preceding claim in the form of a cream, gel, ointment, paste, or lotion for topical application.

8. A pharmaceutical composition substantially as hereinbefore described.